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Promoting physical activity and exercise after stroke using a text messaging intervention (Phase 2)

Submission date
30/03/2021

Recruitment status
No longer recruiting

Registration date
14/04/2021

Overall study status
Completed

Last Edited
10/02/2025

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A stroke is a serious life-threatening medical condition that occurs when the blood supply to part of the brain is cut off. The damage this causes can affect the way your body works, as well as how you think, feel and communicate.
Rehabilitation delivered by physiotherapists is the main intervention for physical recovery immediately post-stroke. After rehabilitation, survivors are signposted to community-based exercise opportunities, walking groups and gyms, and are prescribed home exercises to support recovery. Despite this, 50% of stroke survivors report feeling abandoned and struggle with adherence to exercises for ongoing recovery. Short Message Service (SMS) messages for the delivery of tailored behavioural interventions may support exercise and physical activity adherence after rehabilitation.

The aim of this study (Phase 2) is to pilot test and refine an SMS intervention ready for evaluation in a future feasibility randomised controlled trial. The novel, theoretically informed behaviour change intervention, comprising a series of SMS messages, to support community-dwelling stroke survivors to adhere to personal exercise and PA goals for recovery was co-designed with stroke survivors and rehabilitation professionals in Phase 1.

Who can participate?
Patients aged over 18 years who have had a stroke and are nearing the end of their community rehabilitation period.

What does the study involve?
The study will pilot test and refine the novel SMS intervention in two waves, by delivering it to 44 stroke survivors who are at the end of rehabilitation. Potential participants, identified by rehabilitation therapists, will receive the SMS intervention over 12 weeks. The intervention will be pilot-tested with 14 stroke survivors in Wave 1, then following revisions and refinement, will then be tested with 30 participants in Wave 2.

The personalised SMS messages will be sent by an automated computer system which will be programmed to send out text messages to participants' mobile phones in a predetermined sequence.

Participants will be interviewed by telephone to ascertain their views on the acceptability and usefulness of the intervention. The intervention will be refined using the Collaborative Working Group (CWG) methodology, a formalised stakeholder consultation process. The CWG comprises the research team, stroke survivors, health professionals and academics. A structured decision-making process will be used to revise and refine the intervention, using data available throughout the study (scientific evidence, interview data and field notes). Amendments, made at the end of Phase 2 will provide a final intervention to be tested in a full randomised controlled trial

What are the possible benefits and risks of participating?
The researchers cannot guarantee any benefits, but exercise and physical activity may help with recovery after stroke.

The participants may have impaired mobility and/or balance problems. The greatest potential risk, therefore, is falling. Participants will have been assessed by a health professional (usually a physiotherapist) before being invited to take part in the study, and will only be invited if it is deemed safe for them to take part. They will also receive information on how to reduce the risk of falls and how to manage if they have a fall.

Risks posed by COVID-19 are minimised, as all contact with participants will be by telephone and text communication.

When is the study starting and how long is it expected to run for?
October 2020 to February 2023

Where is the study run from?
The study is run from the University of Dundee, Scotland. Collaborators are based at the University of New Brunswick and the University of St Andrews (UK).

Who is funding the study?
The Chief Scientist Office, Scottish Government, UK

Who is the main contact?
Dr Jacqui Morris
J.Y.Morris @dundee.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
291668

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2-003-2021, IRAS 291668

Study information

Scientific Title
Keeping Active with Texting after Stroke

Acronym
KATS

Study objectives
A behaviour change SMS intervention, delivered over 12 weeks, will support community dwelling stroke survivors to continue with exercise and physical activities to improve recovery, physical activity levels and quality of life after discharge from rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/03/2021, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458;nosres@nhs.net), ref: 21/NS/0028

Study design
Interventional non-randomized development study

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Maintenance of physical activity in people who have had a stroke and are coming to the end of community rehabilitation

Interventions
This is an intervention development study to co-produce an SMS behaviour change intervention in conjunction with stroke survivors and health professionals. The study will undertake preliminary testing of this novel intervention, which will be further developed and refined during the study using formalised stakeholder engagement methods.

The novel SMS intervention will be delivered to the stroke survivors over a 12-week period. Participants will receive at least one text message per day throughout the intervention period. The intervention is designed to support stroke survivors to continue with rehabilitation exercise and physical activities post-rehabilitation.

This is an intervention development study, so no comparator group will be used.

Intervention Type
Behavioural

Primary outcome measure
Engagement of participants with the SMS intervention, assessed by their text message responses to the intervention, telephone interviews at six weeks post-recruitment and at the end of the intervention period. Interviews will seek participants' views on the intervention to refine it for future testing in a randomised controlled trial.

Secondary outcome measures
Acceptability of the intervention, assessed using semi-structured interviews six weeks post-recruitment and at the end of the intervention period

Overall study start date
01/10/2020

Completion date
28/02/2023

Eligibility

Key inclusion criteria

Stroke survivors who:
1. Live in the community
2. Are over 18 years of age
3. Have access to and can use a mobile phone
4. Can provide informed consent
5. Have no contraindications to increasing physical activity
6. Have discussed goal setting with their therapist before discharge from rehabilitation services

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
44

Total final enrolment
44

Key exclusion criteria
Stroke survivors who:
1. Are unable to participate in the study over a 12-week period
2. Have medical conditions contraindicating increased physical activity or specific rehabilitation exercises
3. Cannot communicate verbally (over the telephone or face to face). These people will be excluded for this phase of the study because it involves providing informed consent, discussing the content of the intervention and giving advice on how to improve it, completing questionnaires by telephone

Date of first enrolment
19/04/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
School of Health Sciences
University of Dundee
11 Airlie Place
Dundee
United Kingdom
DD14HJ

Sponsor information

Organisation
University of Dundee

Sponsor details
TASC Research & Development Office
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DD1 9SY
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Sponsor type
University/education

Website
http://www.tasc-research.org.uk

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief

Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers intend to publish a paper on the development of the intervention in a scientific peer-reviewed journal, and will disseminate their findings at academic conferences, NHS events, and within our local research community.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jacqui Morris (j.y.morris@dundee.ac.uk). Type of data: structured Interview transcripts. The researchers will be using the data to inform future studies, so envisage that it would be two years after the end of the study, 31/07/2024, before they would be willing to share the data, and it will be available for five years thereafter. Only researchers who are undertaking intervention development studies of behavioural interventions after stroke, and wish to investigate appropriate adaptations for intervention acceptability by undertaking secondary analysis, may access the data on request to the principal investigator, for qualitative data analysis using framework method or other relevant analysis approaches. Consent was obtained in the participant consent forms by asking the participant to agree to the statement “information about me may be used in other research, but the information will not use my name.” All transcripts will be anonymised with any identifying information removed.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v3.0	15/03/2021	04/05/2021	No	Yes
Plain English results			06/04/2023	No	Yes
HRA research summary			28/06/2023	No	No
Other publications	Development of intervention	23/06/2023	19/10/2023	Yes	No
Other publications	Qualitative study version 1.0	06/07/2023	19/10/2023	Yes	No

Protocol file	16/02/2021	21/06/2024	No	No
Basic results		09/01/2025	No	No
Results article	08/02/2025	10/02/2025	Yes	No